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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,555	03/30/2004	Matthew D. Linnik	252312008000	7418

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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
10/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,555	LINNIK ET AL.	
	Examiner	Art Unit	
	FEREYDOUN G. SAJJADI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27,31,36 and 41-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,31,36 and 41-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/14/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission and amendment filed on May 14, 2008, that includes a response to the office action dated November 14, 2007, has been entered. Claims 1-26, 28-30, 32-35 and 37-40 were cancelled. Claims 27, 31, 36 and 41 have been amended, and claims 42-61 newly added. Accordingly, claims 27, 31, 36 and 41-61 are pending in the application and are under current examination.

Response & New Claim Rejections - 35 USC § 112- Second Paragraph

Applicants' claim amendments have necessitated the following new grounds of rejection.

Claims 1-6, 10-19, 23-28, 30, 33 and 34 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite, in the previous office action dated November 14, 2007. Applicants' cancellation of claims 1-6, 10-19, 23-26, 28, 30, 33 and 34 renders their rejection moot. Applicants' amendment of claim 27, removing the indefinite language obviates the ground of rejection. Thus, the rejection is hereby withdrawn. However, claim 27 is subject to a new ground of rejection, as set forth below:

Claims 27, 31, 36 and 41-61 are newly rejected for employing indefinite language. The claims are unclear in the recitation of time lines corresponding to at least two months (claims 27, 47, 51 and 53-55), at least six months (claim 56 and at least one year (claim 57), because the time periods fail to define an upper limit for sustained reduction of circulating anti-ds DNA antibodies, and thus fail to define the metes and bounds of the claims.

Claims that depend from base claims 27, 47, 51 and 53 have been included in the rejection, as their language fails to obviate the ground of rejection.

Response to Claim Rejections - 35 USC § 112- New Matter

Claims 1-6, 10-19 and 23-41 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement and introducing new matter, in the previous office action dated November 14, 2007. Applicants' cancellation of claims 1-6, 10-19, 23-26, 28-30, 32-35 and 37-40 renders their rejection moot. Applicants' amendment of claims 27, removing the new matter obviates the ground of rejection. Thus, the rejection is hereby withdrawn.

Response & New Claim Rejections - 35 USC § 112-Scope of Enablement

Applicants' claim amendments have necessitated the following new grounds of rejection.

Claims 1-6, 10-19 23-26 and 27-41 stand rejected under 35 U.S.C.§112, first paragraph, because the specification fails to provide an enablement for the full scope of the claimed invention. Applicants' cancellation of claims 1-6, 10-19, 23-26, 28-30, 32-35 and 37-40 renders their rejection moot. The rejection set forth on pp. 3-5 of the office action dated February 26, 2007, and pp. 5-6 of the previous office action dated November 14, 2007 is maintained for claims 27, 31, 36 and 41, and further applied to newly added claims 42-61, for reasons of record.

The previous office action indicated that the instant specification fails to provide an enablement for a method of treating systemic lupus erythematosus (SLE) and reducing the risk of renal flare in any human individual following the administration of LJP-394, resulting in an indefinitely sustained reduction in anti-dsDNA antibody; that the introduced limitations fail to address the issue of treatment in any human individual, or in any human population following the administration of an effective amount of LJP-394; and that the patient population that responded to the treatment regimens with LJP 394 in a statistically significant manner was limited to the sub-population of SLE patients having high affinity antibodies to LJP 394. Further the sustained reduction in antibodies to ds-DNA as depicted in Figures 3 and 4 are limited to the clinical study

period and wherein LJP 394 is administered throughout. Furthermore, the phase II/III 90-05 clinical trials summarized in the prior art of Wallace (Exp. Opin. Invest. Drugs 10:111-117; 2001) indicated that the results of the clinical studies may not be extended to all SLE patients and a sustained reduction in anti-ds-DNA antibodies in a sub-population of SLE patients has not been demonstrated for an indefinite period of time.

Applicants traverse the rejection, stating that amendments have been made to claims 27, 31, 36 and 41; and that claim 27 now requires the step of "determining if there is a sustained reduction of circulating anti-dsDNA antibodies in the individual of at least 10% below baseline for at least two months, wherein said sustained reduction indicates the effectiveness of the treatment."; that new independent claims 47, 51, or 53 contain similar "determination" steps, thus the determination for sustained reduction of anti-dsDNA antibody is for the recited period of time. Applicants' arguments have been fully considered, but are not found persuasive.

The claim amendments fail to obviate the grounds for rejection, because the sustained reduction of circulating anti-dsDNA antibody for at least two months, at least six months, and at least one year, fail to set an upper limit for the duration of antibody reduction and includes an indefinite period of sustained treatment. Applicants have additionally failed to address the issue of the treatment group limited to those having high affinity IgG antibodies to LJP-394.

Thus it is maintained that the specification is only enabling for a method of treating (SLE) and reducing renal flare in a subpopulation of human individuals characterized by having high affinity IgG antibodies to LJP-394, comprising administering to said individuals an effective amount of LJP-394 to reduce the levels of anti-dsDNA antibodies.

Thus, the rejection is maintained for claims 27, 31, 36 and 41, and further applied to newly added claims 42-61, for reasons of record and the foregoing discussion.

Response & New Claim Rejections - 35 USC § 102

Applicants' claim amendments have necessitated the following new grounds of rejection.

Claims 1-6, 10-19 and 23-41 stand rejected under 35 U.S.C. 102(b) as being anticipated by Wallace (Exp. Opin. Invest. Drugs 10:111-117; 2001). Applicants' cancellation of claims 1-6,

10-19, 23-26, 28-30, 32-35 and 37-40 renders their rejection moot. The rejection set forth on pp. 6-7 of the office action dated February 26, 2007, and pp. 6-7 previous office action dated November 14, 2007 is maintained for claims 27, 31, 36 and 41, and further applied to newly added claims 42-61, for reasons of record.

Applicants traverse this rejection and state that claims 27, 31, 36 and 41 have been amended, and Wallace fails to anticipate amended independent claim 27, because it does not teach a method of treating systemic lupus erythematosus (SLE) comprising determining if there is a sustained reduction of circulating anti-dsDNA antibodies in the individual of at least 10% below baseline for at least two months, wherein said sustained reduction indicates the effectiveness of the treatment. Applicants put forth similar arguments regarding the limitations of claims 47, 51 and 53. Applicants' arguments have been fully considered, but are not found persuasive.

In response, it should be noted that the rejection of the claims over the prior art of Wallace is applicable only to the extent that the instant claims have been indicated as enabled. Therefore, the citation of prior art is commensurate with the enabled scope indicated for the instant claims. In so far as the instant claims encompass the active step of administering of an effective amount of the agent LJP394 (the instantly claimed conjugate), to a human individual to treat SLE and renal flare, Wallace teaches the same. Wallace et al. further teach the results and clinical effects and efficacy of LJP394 in Phase I-III studies and clinical trials in lupus patients, following administration of various dosing regimens and the determination of the effects on anti-ds-DNA levels; further stating: "In patients receiving 10 and 50 mg of LJP-394 weekly, concentration of antibodies of ds-DNA were significantly reduced from baseline until 8 weeks from the last dose." (second column, p. 114). Additionally taught are the effects of 10, 50 and 100 mg of LJP-394 weekly for 12 weeks on anti-ds-DNA (first column, p. 115). Wallace et al. further teach a 76-week trial of repeated doses of LJP-394, with the primary end-point of whether treatment elevated renal flares, and the secondary objective of whether LJP-394 treatment reduced anti-ds-DNA antibody concentration and reduced the symptoms of SLE, or improved quality of life (first column, p. 115). It is further noted that the amount of reduction in

the anti-ds DNA antibodies of at least 10% below baseline would necessarily result from the administration of an effective amount of LJP-394, and would be a property inherent to the agent.

Thus, the rejection is maintained for claims 27, 31, 36 and 41, and further applied to newly added claims 42-61, for reasons of record and the foregoing commentary.

Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27, 31, 36 and 41-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of copending U.S. Patent Application No.: 11/562,174, in view of Wallace (Exp. Opin. Invest. Drugs 10:111-117; 2001). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '174 Application are directed to a method of stabilizing or improving the quality of life of an individual with SLE, and renal flare, comprising administering to the individual an effective amount of a ds DNA epitope in the form of a conjugate comprising a non-immunogenic valency platform molecule, having the formula instantly claimed. With respect to sustained reduction of circulating anti-ds antibodies below baseline, Wallace discloses the same.

Therefore, to practice the instant invention, it would have been obvious to one of ordinary skill in the art that the claimed methods for administering the compound composition in the '174 Application and the disclosure of Wallace are reasonably embraced by the methods recited in the instant claims. Thus, claims 1-39 of copending U.S. Patent Application No.: 11/384,191 and claims 27, 31, 36 and 41-61 of the instant application are obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 27, 31, 36 and 41-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 12-21, 25 and 26 of copending U.S. Patent Application No.: 11/565,467, in view of Wallace (Exp. Opin. Invest. Drugs 10:111-117; 2001). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '467 Application are directed to a method of treating SLE in an individual, comprising administering to the individual an effective amount of a ds DNA epitope in the form of a conjugate comprising a non-immunogenic valency platform molecule, having the formula instantly claimed. With respect to sustained reduction of circulating anti-ds antibodies below baseline, Wallace discloses the same.

Therefore, to practice the instant invention, it would have been obvious to one of ordinary skill in the art that the claimed methods for administering the compound composition in the '567 Application and the disclosure of Wallace are reasonably embraced by the methods recited in the instant claims. Thus, claims 1-8, 12-21, 25 and 26 of copending U.S. Patent Application No.: 11/565,467 and claims 27, 31, 36 and 41-61 of the instant application are obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 27, 31, 36 and 41-61 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/
Fereydoun G. Sajjadi, Ph.D.
Examiner, Art Unit 1633